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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,727	07/08/2002	Hubert Rein	228.1010	8812

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,727	REIN ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *5,8 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 5, 8, and 17 are objected to because of the following informalities: Claim 5 is drawn to a water-soluble matrix. However, Claim 14 is drawn to a water-insoluble matrix, and the instant specification discloses that a preferred embodiment of the instantly claimed invention is a water-insoluble matrix. Claim 8 is drawn to a release profile that "may be adjusted over 24 hours or more". Claim 17 is drawn to a release profile that "is adjusted over a period of up to 24 hours or longer". The instant specification discloses that a preferred release profile "is adjustable over 24 hours or longer".

The examiner perceives an apparent disconnect and lack of correspondence in the claimed subject matter. Clarification is requested. In order to advance prosecution, Claim 5 will be treated as if it were drawn to a water-insoluble matrix.

Claim Rejections - 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 2 and 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 19 provides for the use of a dosage form, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In order to advance prosecution, Claim 19 will be treated as a method of manufacture.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentz *et al.* (WIPO Document No. WO 92/15285)

The Lentz *et al.* document discloses controlled-release starch compositions (See Abstract). The compositions comprise a melt made from a starch/water mixture and an active ingredient. The starch is processed in such a way as to eliminate a granular starch structure, rendering it "destructured" (See Page 11, Line 8 to Page 12, Line 30; and Page 17, Line 34 to Page 18, Line 15). This allows for greater compressibility in the formation of tablets (See Page 15, Lines 8-14). Various types of drugs, either water-soluble or -insoluble, may be incorporated into the disclosed controlled-release starch matrices (See Page 15, Line 25 to Page 16, Line 39). Various types of dosage forms, including tablets, capsules, beads, granules, powders, and solids may be formulated from the compositions. Processing techniques that may be used to produce such dosage forms include wet and dry granulation, injection molding, thermoforming, extrusion, co-extrusion, and cast molding (See Page 26, Line 29 to Page 27, Line 21). Release profiles are given which show the release of an active ingredient over a period of 24 hours. The release profile of the active ingredient appears to follow a lapidus function (See Figures 2 & 3).

Although the disclosed release profiles only show drug release up to a period of 24 hours, the amount of drug released in some figures remain under 100%. It is the position of the examiner that drug release can continue beyond 24 hours and that this release profile is due to the insolubility of the amorphous starch matrix. Therefore, it is the position of the examiner that the limitations of Claims 5, 8, 14, and 17 are inherent to the compositions disclosed in Lentz *et al.* Furthermore, given the wide variety of active ingredients that may be incorporated into the

disclosed amorphous starch matrix of varying solubility characteristics, it is the position of the examiner that the limitations of Claims 9 and 18 would also be inherent to the compositions disclosed in Lents *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 8, 9, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz *et al.*

The relevant portions of Lentz *et al.* is given in the above rejection of Claims 1-19 under 35 U.S.C. 102(b).

As Claims 5, 8, 9, 14, 17, and 18 are rejected for containing subject matter that, in the view of the examiner, is inherent to the disclosure of the prior art, a rejection under 35 U.S.C. 103(a) is deemed proper.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
May 1, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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